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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,710	04/22/2005	Takeshi Ito	KUZ-0022	5270
Kathleen Tyrrell Licata & Tyrrell 66 East Main Street Marlton, NJ 08053			EXAMINER ELLIS, SUEZU Y	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			12/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/527,710

Applicant(s)

ITO ET AL.

Examiner

Suezu Ellis

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/11/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not

extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 11, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

The abstract of the disclosure is objected to because the abstract recites "the ratio of the concentration of the polyisobutylene to that of the styrene/isoprene/styrene block copolymer being from 2/3 to 3/2". The ratios should be written with colons, not backslashes. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

The ratios in the last line of page 6 should be written with colons and not backslashes for proper consistency with the ratios on page 3.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (US 6,139,866) in view of Tsuruda et al. (CA 2 424 579).

With respect to claims 1 and 2, Chono et al. discloses an adhesive patch comprising a backing layer and a pressure-sensitive adhesive layer formed on one side thereof (col. 5, lines 39-43), wherein the pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive base (col. 5, lines 19-22) and a tackifier resin (col. 3, lines 44-54). Chono et al. discloses in Example 6, fentanyl as an active ingredient in the concentration of 5% by weight (in the range of 1-6% by weight), and the pressure-sensitive adhesive base comprising polyisobutylene and a styrene/isoprene/styrene block copolymer. While Example 6 fails to illustrate the weight ratio of polyisobutylene and styrene/isoprene/styrene being in the range between 2:3 and 3:2, Chono et al. discloses the weight ratio of polyisobutylene to styrene/isoprene/styrene is in the range of 1:1 and 1:4 (col. 3, lines 9-10), the claimed weight ratio can be attained. However, Chono et al. also fails to expressly disclose the proportion of the polyisobutylene in the adhesive base being between 8 and 15% by weight. Tsuruda et al. discloses an adhesive patch having combination of styrene/isoprene/styrene block copolymer and polyisobutylene (pg. 23, lines 20-24). Tsuruda et al. discloses the total amount of polyisobutylene be in the range of 1-20% by weight (pg. 21, lines 9-13) and the amount of styrene/isoprene/styrene block copolymer being in the range of 15-30% by weight (pg. 20, lines 16-21), thus demonstrating the proportion of the polyisobutylene being 8-

15% by weight and a ratio of the concentration of the polyisobutylene to that of the styrene/isoprene/styrene block copolymer being in the range from 2:3 to 3:2 are attainable. It would have been an obvious design choice to one of ordinary skill in the art to modify the amount of the polymers, as desired, in order to adjust the adhesive strength and adhesion properties, as taught by Tsuruda et al. (pg. 23, line 10 - pg. 24, line 20). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discover the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 3, the modified Chono et al. fails to expressly disclose the polyisobutylene consisting of a high molecular weight polyisobutylene and a low molecular weight polyisobutylene. Tsuruda et al. discloses an adhesive patch having a styrene/isoprene/styrene block copolymer and a combination of polyisobutylenes having high and low molecular weights, wherein the low molecular weight polyisobutylene is Vistanex LM-MH and the high molecular weight polyisobutylene is Vistanex MML-100 (pg. 21, lines 9-24; pg. 22, lines 10-12). It would have been obvious to one of ordinary skill in the art to utilize a combination of polyisobutylenes having high and low molecular weights in order to achieve the predictable result of improving the adhesive strength, adhesion to the skin for a long time, pain at the time of peeling, skin eruptions etc. (pg. 22, lines 19-24).

With respect to claim 7, while Example 6 fails to illustrate the tackifier resin being in the range of 40-50% by weight, Chono et al. does disclose the tackifier resin being in the range from 5-50% by weight (col. 3, lines 56-60) and Example 7 demonstrates an



adhesive patch of a similar composition having a tackifier resin at 42% by weight. It would have been obvious to one of ordinary skill in the art to modify the range of the tackifier resin, as desired, in order to regulate the viscosity and adhesive strength of the adhesive base, as taught by Tsuruda et al. (pg. 25, lines 9-25). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 8 and 9, the modified Chono et al. discloses the inclusion of a percutaneous absorption enhancer in the pressure-sensitive adhesive layer, wherein the percutaneous absorption enhancer is one or more selected from a group consisting of isopropyl myristate and oleyl alcohol (col. 4, lines 6-8, 22-23).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (US 4,031,894).

With respect to claim 4, the modified Chono et al. addresses all the limitations of claims 1 and 3, however fails to expressly disclose the average molecular weight of the high molecular weight polyisobutylene being in the range of 900,000-2,500,000. Nevertheless, it is well known in the art that Vistanex MML-100 has an average molecular weight about 1,200,000, as evidenced by Urquhart et al. (col. 6, lines 10-12), thus is in the range of 900,000-2,500,000.



Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (US 5,750,136).

With respect to claim 5, the modified Chono et al. addresses all the limitations of claims 1 and 3, however fails to expressly disclose the average molecular weight of the low molecular weight polyisobutylene being in the range of 30,000 – 65,000. Nevertheless, it is well known in the art that Vistanex LMMH has an average molecular weight about 53,000, as evidenced by Scholz et al. (col. 6, lines 21-23), thus is in the range of 30,000 – 65,000.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Higo et al. (US 5,866,157)

With respect to claim 6, while Example 6 fails to illustrate the tackifier resin being an alicyclic saturated hydrocarbon resin, the modified Chono et al. does disclose the tackifier can be Arcon P-100 (col. 3, lines 51-53). It is well known in the art that Arcon P-100 is an alicyclic saturated hydrocarbon resin, as evidenced by Higo et al. (Example 2).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zaffaroni (US 3,598,122) and further in view of Kochinke (US 5,350,581).

With respect to claim 10, the modified Chono et al. addresses all the limitations of claim 1, however fails to expressly disclose the adhesive patch having an area of 10-

75 cm<sup>2</sup> at the time of application. Zaffaroni discloses utilizing a transdermal bandage having a surface area of 0.5 to 400 cm<sup>2</sup>, where the size is dependent on the activity of the drug and the rate of its absorption through the skin (col. 6, lines 25-29). It would have been an obvious design choice to one of ordinary skill in the art to modify the surface area of the adhesive patch in order to ensure that the amount of drug entering the system appropriate for the treatment was safe and efficacious, as taught by Kochinke (US 5,350,581) (col. 1, lines 17-20).

***Telephone/Fax Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SE

  
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